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UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF TEXAS

JAMES HUDDLESTON, INDIVIDUALLY AND ON BEHALF OF THE ESTATE OF PATRICIA HUDDLESTON-BROWNFIELD AND ALL LEGAL BENEFICIARIES; Plaintiffs, vs. MALLINCKRODT, INC. Defendant.	Case No: ORIGINAL COMPLAINT DEMAND FOR JURY TRIAL

Plaintiff JAMES HUDDLESTON, individually and on behalf of the estate of PATRICIA HUDDLESTON-BROWNFIELD and ALL LEGAL BENEFICIARIES (hereinafter "Plaintiffs") allege as follows:

NATURE OF THE CASE

1. Decedent Patricia Huddleston-Brownfield ("Mrs. Huddleston-Brownfield" or "Decedent") had Nephrogenic Systemic Fibrosis ("NSF"). NSF is an incurable, painful, and deadly disease. Mrs. Huddleston-Brownfield contracted NSF as a result of receiving intravenous injections of

gadolinium-based contrast agents manufactured by the Defendant. Gadolinium-based contrast agents are not safe for use in individuals such as Decedent who have impaired kidney function. Defendant represented that the gadolinium-based contrast agents were safe and failed to warn of the risks associated with gadolinium-based contrast agents.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 USC § 1332. Plaintiffs are citizens of a state that is different from the states where Defendant is incorporated and have their respective principal places of business. The amount in controversy for this case exceeds $75,000. Venue pursuant to 28 USC § 1391(b) is proper because Defendant has sufficient contacts within the Polk County Texas to subject each of them to personal jurisdiction.

PARTIES

Plaintiffs

1. PATRICIA HUDDLESTON-BROWNFIELD ("Decedent") was a resident of the State of Texas in Polk County until her death.

2. Plaintiff JAMES HUDDLESTON, the son, heir, and executor the estate of Decedent, is a resident of the State of Texas in Polk County

Defendant

3. Defendant Mallinckrodt, Inc. manufactures, markets, and sells OptiMARK, a gadolinium-based contrast agent that, on information and belief, was injected into Decedent.

4. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business in Missouri.

5. At all times relevant to this complaint, Mallinckrodt was in the business of designing, licensing, manufacturing, distributing, selling, marketing, promoting, and introducing OptiMARK into interstate commerce.

FACTS

6. Decedent had NSF.

7. NSF is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and

edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF is a progressive disease for which there is no known cure.

8. NSF is a man-made disease. It only occurs in patients who have received a gadolinium-based contrast agent.

9. Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.

10. Because gadolinium is toxic, it has to be coated to keep it from coming in contact with human tissue when injected. This coating process is called chelation.

11. Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast agents are not safe if the chelate separates from the gadolinium, which is what happens over time if kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation, and cannot efficiently or quickly eliminate gadolinium from their bodies. Defendant never tested the safety of their gadolinium-based contrast agents in individuals with kidney impairment.

12. On information and belief, the gadolinium-based contrast agents injected into Decedent were manufactured by Defendant.

13. In pre-clinical studies during which gadolinium-based contrast agents were injected into laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the kidneys and other body organs occurred.

14. During the years that Defendant has manufactured, marketed, distributed, sold, and administered gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, and other clinical data that have described and/or demonstrated NSF in connection with the use of gadolinium-based contrast agents.

15. Decedent received MRIs and/or MRAs utilizing gadolinium-based contrast agents.

16. Decedent had impaired kidney function at the time he received her first injection of gadolinium-based contrast agent and continued to have impaired kidney function at the time she received each subsequent injection of gadolinium-based contrast agent.

17. During the time period when Decedent received injections of Defendant's gadolinium-based contrast agents, Defendant knew or should have known that the use of gadolinium-based contrast agents created a risk of serious bodily injury and death in patients with impaired kidney function.

18. Defendant failed to warn Decedent and her healthcare providers about the serious health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives.

19. As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, marketed, distributed, and sold by Defendant, Decedent developed NSF.

20. Defendant has repeatedly and consistently failed to advise consumers and/or their healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in patients with kidney impairment. Defendant knew or should have known of the risk of NSF posed by gadolinium-based contrast agents to individuals with impaired kidney function years before they finally issued warnings.

21. It was not until September 2007 that Mallinckrodt, along with three other manufacturers of gadolinium-based contrast agents, finally sent letters to healthcare providers warning them of the risk of NSF to kidney-impaired individuals who received MRIs using gadolinium-based contrast agents.

22. Had Decedent and/or her healthcare providers been warned about the risks associated with gadolinium-based contrast agents, she would not have been administered gadolinium-based contrast agents and would not have been afflicted with NSF.

23. As a direct and proximate result of Decedent being administered gadolinium-based contrast agents, she suffered severe physical injury and pain and suffering, including, but not limited to, the effects of NSF and death.

24. As a direct and proximate result of being administered gadolinium-based contrast agents, Decedent and Plaintiffs suffered significant mental anguish and emotional distress and Plaintiffs will continue to suffer significant mental anguish and emotional distress in the future.

25. As a direct and proximate result of being administered gadolinium-based contrast agents, Decedent and Plaintiffs have also incurred medical expenses and other economic damages.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

26. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against Defendant. The nature of Decedents' injuries and damages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiffs, until a time less than two years before the filing of this Complaint. It was not until January 2013 that Plaintiffs learned Decedent's previously misdiagnosed skin condition was actually NSF. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

27. Defendant is estopped from asserting a statute of limitations defense because all Defendant fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and all Defendant' tortious conduct.

FIRST CAUSE OF ACTION
STRICT LIABILITY: FAILURE TO WARN

28. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

29. Defendant's gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendant knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendant failed to adequately warn consumers and their healthcare providers of such

risks.

30. Because of Defendant's failure to provide adequate warnings with their products, Decedent was injected with gadolinium-based contrast agents that the Defendant manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents are the legal cause of Decedent's physical injuries, harm, damages, economic loss and death, and of the damages of Plaintiff as set forth below.

SECOND CAUSE OF ACTION
STRICT LIABILITY: DESIGN DEFECT

31. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

32. Defendant is the manufacturer, designer, distributor, seller, or supplier of gadolinium-based contrast agents, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

33. The gadolinium-based contrast agent manufactured and supplied by Defendant was defective in design or formulation in that, when they left the hands of the Defendant, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or were more dangerous than an ordinary consumer would expect.

34. The foreseeable risks associated with the design or formulation of gadolinium-based contrast agent, and MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents, include, but are not limited to, the fact that the design or formulation of gadolinium-based contrast agents are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

35. As a direct and proximate result of Decedent being administered gadolinium-based contrast agent as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendant, Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

THIRD CAUSE OF ACTION
STRICT LIABILITY: FAILURE TO ADEQUATELY TEST

36. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

37. Defendant advised consumers and the medical community that gadolinium-based contrast agents were safe for use. Defendant failed to adequately test gadolinium-based contrast agents with respect to their use by consumers with kidney impairment.

38. Had Defendant adequately tested the safety of gadolinium-based contrast agents for use by consumers with kidney impairment and disclosed those results to the medical community or the public, Decedent would not have been administered gadolinium-based contrast agents.

39. As a direct and proximate result of Defendant' failure to adequately test the safety of gadolinium-based contrast agents and as a direct and proximate result of Decedent being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendant, Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

FOURTH CAUSE OF ACTION
NEGLIGENCE

40. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

41. Defendant had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

42. Defendant failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew or should have known that the products could cause significant bodily harm or death and were not safe for use by certain types of consumers.

43. Defendant failed to exercise ordinary care in the labeling of gadolinium-based contrast agents and the labeling of MRI and MRA machines designed to be used in conjunction with

gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

44. Despite the fact that Defendant knew or should have known that gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendant unreasonably continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents for administration to MRI and MRA patients with kidney impairment and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

45. At all relevant times, it was foreseeable to Defendant that consumers like Decedent would suffer injury as a result of their failure to exercise ordinary care as described above.

46. As a direct and proximate result of Defendant's negligence, Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

47. The foregoing acts, conduct and omissions of Defendant were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Decedent and other users of Defendant' products, and for the primary purpose of increasing Defendant' profits. As such, Plaintiffs are entitled to exemplary damages.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

48. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

49. Defendant supplied the public and Decedent's healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents.

50. The false information supplied by Defendant was that gadolinium-based contrast agents were safe.

51. In supplying this false information, Defendant failed to exercise reasonable care.

52. The false information communicated by Defendant to Decedent and her healthcare providers was material and Decedent justifiably relied in good faith on the information to her detriment.

53. As a direct and proximate result of Defendant's misrepresentations, Decedent was administered gadolinium-based contrast agents and Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages, and economic loss.

SIXTH CAUSE OF ACTION
FRAUD

54. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

55. Defendant knowingly and intentionally made materially false and misleading representations to Decedent's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing, and promotional materials fully described all known risks associated with their product.

56. Defendant' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendant' labeling, marketing, and promotional materials did not fully describe all known risks of the products.

57. Defendant had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with kidney impairment.

58. Defendant knowingly and intentionally omitted their information from their labeling, marketing, and promotional materials and instead, labeled, promoted, and marketed their products as safe for use in order to increase and sustain sales.

59. When Defendant made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Decedent, her healthcare providers, and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with kidney impairment.

60. Defendant had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with kidney impairment. Defendant had superior knowledge of these facts that were material to Decedent and her healthcare providers' decisions to use gadolinium-based contrast agents.

61. Decedent and her healthcare providers reasonably and justifiably relied on the Defendant' representations that gadolinium-based contrast agents were safe for human use and that Defendant' labeling, marketing, and promotional materials fully described all known risks associated with the products.

62. Decedent did not know and could not have learned of the facts that the Defendant omitted and suppressed. The facts suppressed and concealed by the Defendant are material. Had Decedent and her healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Decedent would not have been injected with gadolinium-based contrast agents.

63. As a direct and proximate result of Defendant's misrepresentations and concealment, Decedent was administered gadolinium-based contrast agents, suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

64. The foregoing acts, conduct, and omissions of Defendant were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Decedent and other users of Defendant's products, and for the primary purpose of increasing Defendant' profits. As such, Plaintiffs are entitled to exemplary damages.

SEVENTH CAUSE OF ACTION
FRAUD: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS

65. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

66. Defendant omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Defendant purposely downplayed and understated the serious nature of the risks

associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.

67. As a direct and proximate result of Defendant's concealment of material facts, Decedent was administered gadolinium-based contrast agents, suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

68. The foregoing acts, conduct, and omissions of Defendant were vile, base, willful, malicious, wanton, oppressive, and fraudulent, and were done with a conscious disregard for the health, safety, and rights of Decedent and other users of Defendant's products, and for the primary purpose of increasing Defendant' profits. As such, Plaintiffs are entitled to exemplary damages.

EIGHTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

69. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

70. Defendant expressly warranted that gadolinium-based contrast agents were safe and effective.

71. The gadolinium-based contrast agents manufactured and sold by Defendant did not conform to these express representations because they cause serious injury to consumers when administered in recommended dosages.

72. As a direct and proximate result of Defendant's breach of warranty, Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

NINTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

73. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

74. At the time Defendant designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendant knew of the use for which gadolinium-based contrast agents was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

75. Decedent reasonably relied upon the skill and judgment of Defendant as to whether

gadolinium-based contrast agents were of merchantable quality and safe for their intended use and upon Defendant' implied warranty as to such matters.

76. Contrary to such implied warranty, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the product was unreasonably dangerous as described above.

77. As a direct and proximate result of Defendant's breach of warranty, Decedent suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

TENTH CAUSE OF ACTION
VIOLATION OF TEXAS DECEPTIVE TRADE PRACTICES CONSUMER PROTECTION ACT

78. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

79. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§ 17 et seq. including but not limited to the following:

a. Marketing, promoting or selling OptiMark for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;

b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;

c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not;

d. Marketing, promoting, or selling their products as safer or superior to other brands of gadolinium-based contrast agents;

e. Marketing, promoting or selling OptiMark as inert or with words to that effect;

f. Marketing, promoting or selling OptiMark for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

g. Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.

80. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive actions or practices, Decedent was administered gadolinium-based contrast agents, suffered physical injuries, harm, damages, economic loss and death, and Plaintiffs suffered and continue to suffer such harm, damages and economic loss.

ELEVENTH CAUSE OF ACTION
WRONGFUL DEATH

81. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

82. As a proximate result of the conduct of Defendant, as described above, Decedent suffered from death, personal injuries and other economic and non-economic damages.

83. Pursuant to Tex. Civ. Prac. & Rem. Code Ann. §71.002 and all applicable Texas law, Plaintiff JAMES HUDDLESTON pursues a wrongful death action on behalf of all legal beneficiaries for recovery of all damages permitted under Texas law.

TWELTH CAUSE OF ACTION

SURVIVAL ACTION

84. Plaintiffs incorporate by reference and reallege each paragraph set forth above.

85. PATRICIA HUDDLESTON-BROWNFIELD, had she lived, would have had causes of action against Defendant as alleged above.

86. As a proximate result of the conduct of Defendant as described above, PATRICIA HUDDLESTON-BROWNFIELD suffered personal injuries, pain, suffering, and other damages.

87. Pursuant to Tex. Civ. Prac. & Rem. Code § 71.021 governing survival claims and all applicable Texas law, Defendant are liable for damages to JAMES BROWNFIELD individually and on behalf of the Estate of PATRICIA HUDDLESTON-BROWNFIELD.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic

damages in an amount to be determined at trial of this action;

2. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;

3. Punitive damages in an amount to be determined at trial of this action;

4. Pre- and post-judgment interest;

5. Attorneys' fees, expenses, and costs; and

6. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Respectfully submitted this on the 24th day of December, 2014.

By: _____

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